

and claim 13 (now claim 14) as outlined in Appendix A, attached herewith.

#### **REMARKS**

After entry of the above amendment, claims 6-11 and 13-17 will be pending in this application. The amendment to the claims does not add any new matter.

Applicants respectfully note that there were two occurrences of claim 5 in the previous claim set. Furthermore, applicants respectfully note that the Examiner renumbered claim 5 (second occurrence) as claim 6 and the subsequent claims as claims 7-24. Applicants adopt the numbering applied by the Examiner hereinafter.

#### **1. Rejection of claims 1-6 under 35 U.S.C §102(e)**

The Official Action states that claims 1-6 are rejected under 35 U.S.C. §102(e) as being anticipated by Keller, et al.

#### **RESPONSE**

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

First, applicants respectfully note that claims 1-5 (first occurrence) have been canceled without prejudice, rendering the basis for this rejection moot. Thus, the only remaining rejection is of presently pending claim 6.

With regards to rejected claim 6, applicants respectfully point out to the Examiner that the Keller, et al. reference does not teach each and every element of the presently claimed invention as required by *Verdegaal Bros. v. Union Oil Co. of California*. In particular, presently pending claim 6 recites that the two active compounds, ciclesonide and R,R-formoterol, are present in separate pack units. This feature is not disclosed by the Keller et al. reference. Further, presently pending claim 6 recites that the active compounds are "available for successive inhalative administration". This feature is also not disclosed by the Keller, et al. reference.

Further, applicants take issue with the Examiner's interpretation of the Keller, et al. reference teaching at col. 8, lines 53-59 and col. 1, lines 44-52. The Examiner has stated

at page 4 (last sentence of the first paragraph) of the Official Action that "Preparation of these formulations may result from mixing pharmaceutically active compositions together or separately in any desired sequence (col. 8, lines 53-59); thus accommodating for whether the drug was ready-mixed in a fixed combination or available separately (ie. blister packs, see col. 1, lines 44-52)".

However, the passage in col. 8, lines 53-59 of Keller, et al. appears to be discussing the mixture of a pharmaceutically active compound with a pharmaceutically inactive carrier and magnesium stearate (see col. 8, lines 46-53 immediately preceding the passage cited by the Examiner). Thus, there is no teaching in Keller, et al. regarding the preparation of a pharmaceutical composition containing two pharmaceutically active compounds, each of which are present in separate pack units as presently claimed.

Furthermore, column 1, lines 44-52 of Keller, et al. as cited by the Examiner simply relates to powder inhalers which release the medicament, such as from capsules or blister packs. Nothing is disclosed by Keller, et al. regarding powder inhalers which contain two pharmaceutically active compounds, wherein each of said compounds is present in a separate capsule or blister pack, as presently claimed.

As such, the Keller, et al. reference clearly falls short of teaching each and every element of the presently claimed invention as required by *Verdegaal Bros. v. Union Oil Co. of California*. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection of presently pending claim 6.

**2. Rejection of claims 1-10 and 18-20 under 35 U.S.C. §103(a)**

The Official Action states that claims 1-10 and 18-20 are rejected under 35 U.S.C. §103(a) over Keller, et al. in view of Postma, et al.

**RESPONSE**

Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 167 L.Ed. 705 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to

the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully note that claims 1-5 (first occurrence) and claims 18-20 have been canceled without prejudice. Thus, the remaining rejection is of presently pending claims 6-10.

As discussed above in section 1., the Keller, et al. reference clearly falls short of teaching each and every element of the presently claimed invention. Furthermore, there is no teaching in the Postma, et al. reference that remedies the deficiencies of the Keller, et al. reference. In particular, the Postma, et al. reference does not teach that ciclesonide and R,R-formoterol are present in separate pack units. Also, the Postma, et al. reference does not disclose that two pharmaceutically active compounds may be made available for successive inhalative administration, as presently claimed. Therefore, a combination of the two cited references (the Keller, et al. reference and the Postma, et al. reference) do not teach or suggest all the limitations of presently pending claims 6-10, as required by *In re Wilson*.

As such, the Examiner has failed to demonstrate a *prima facie* case of obviousness against presently pending claims 6-10. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection of pending claims 6-10.

### **3. Rejection of claims 11-17 and 21-24 under 35 U.S.C. §103(a)**

The Official Action states that claims 11-17 and 21-24 are rejected under 35 U.S.C. §103(a) over Postma, et al. or Taylor,

et al. in view of Akpinarli, et al. and Maesen, et al.

**RESPONSE**

Applicants respectfully traverse this rejection. First, applicants respectfully note that claims 12 and 21-24 have been canceled without prejudice. Thus, the remaining rejection is of presently pending claims 11 and 13-17.

Second, the cited references do not teach each and every element of the presently claimed invention as required by *In re Wilson*. In particular, none of these cited references teaches that ciclesonide and R,R-formoterol may be present in separate pack units. Also, the cited references do not disclose that two pharmaceutically active compounds may be made available for successive inhalative administration, as presently claimed.

As such, the Examiner has clearly failed to demonstrate a *prima facie* case of obviousness against the presently pending claims. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection of the pending claims.

**CONCLUSION**

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

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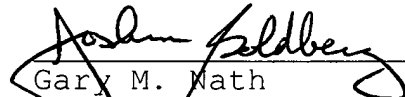
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Respectfully submitted,  
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